



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/540,604

05/15/2006

Carl-Johan Hoijer

P05,0232

9006

26574 7590 04/14/2010

SCHIFF HARDIN, LLP
PATENT DEPARTMENT
233 S. Wacker Drive-Suite 6600
CHICAGO, IL 60606-6473

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,604	Applicant(s) HOIJER, CARL-JOHAN	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 7 and 9-12 have been considered but are moot in view of the new grounds of rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Bakels et al. (US 6,070,100). Bakels et al. discloses an implantable pacemaker that interacts with at least one ventricle and at least one atrium to provide multiple chamber pacing of the patient's heart. Furthermore, the system provides impedance sensing in order to optimize parameters (See figure 2A). Figure 8A depicts a flow diagram of a process using inter-atrial or inter-ventricular impedance measurements for determination of existence of arrhythmias. "If a rhythm is determined not to be regular, then a determination of arrhythmia is made" (col. 10, lines 39-41). The impedance determination assists in the optimization the timing and the delivery of pacing pulses.

"The pacemaker 30 operates under control of circuitry 62, which may include a microprocessor or custom integrated circuitry, as well as associated memory, in a manner well known in the pacemaker art. Circuitry 62 provides for processing of data,

Art Unit: 3762

and generation of timing signals as required. Control circuitry 62 is coupled to pace/sense circuitry 64, for processing of signals indicating the detection of electrical cardiac events, e.g., P-waves, R-waves, etc. sensed from conductors which connect electrically to electrodes 32a-38b, as shown. The aforementioned leads are also coupled to a first switch matrix 68 and a second switch matrix 70. Matrix 68 establishes a selectable interconnection between specific ones of the electrodes of leads 32, 34, 36 and 38, and the current source 72, is controlled by circuit 62. In a similar manner, switch matrix 70 establishes a selectable interconnection between lead conductors corresponding to selected electrodes, and impedance detection circuit 74, for the purpose of selecting impedance measurements”(col. 7, lines 12-30).

“In a heart with normal right heart function, the right mechanical AV delay is monitored to provide the timing between the initial sensing of right atrial activation (P-wave) and right ventricular mechanical contraction. The left heart is controlled to provide pacing which results in left ventricular mechanical contraction in a desired time relation to the right mechanical contraction; e.g., either simultaneous or just preceding the right mechanical contraction; cardiac output is monitored through impedance measurements, and left ventricular pacing is timed to maximize cardiac output. In patients with intra-atrial block, the left atrium is paced in advance of spontaneous depolarization, and the left AV delay is adjusted so that the mechanical contractions of the left ventricle are timed for optimized cardiac output from the left ventricle” (col. 4, lines 14-29). Therefore, Bakels et al. discloses the switch from P-wave synchronous mode in healthy heart (i.e.

Art Unit: 3762

no atrial arrhythmia) to non-P-wave synchronous mode in an unhealthy heart or when an atrial arrhythmia is detected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels et al. (US 6,070,100). Bakels et al. discloses the device substantially as claimed except for the comparison to a reference value and averaging the value over time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to compare the atrial impedance rate to a reference value and to average the value over time in order to provide the predictable results of tracking or monitoring the patients cardiac condition. In addition, comparison to a reference value enhances the optimization of pacing parameters.

2. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels et al. (US 6,070,100) in view of Mann (US 6,052,624). Bakels et al. discloses the device substantially as claimed except for the housing having an electrically conductive area functioning as a return electrode. Mann discloses that it is known to use "an indifferent or return electrode, Eg, which may in fact form part of the case or housing of

Art Unit: 3762

the implantable stimulator" (col. 9, lines 24-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an return electrode on the housing of the implantable medical device in order to provide the predictable results of increasing the electrode surface area as well as streamlining the device by placing an electrode on the surface of the stimulator. Furthermore, using the housing as an electrode, commonly referred to as a "can electrode" is well known in the implantable medical device art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762